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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA and BIOTECHNOLOGY INNOVATION ORGANIZATION,

Plaintiffs,

vs.

BRIAN SANDOVAL, in his official capacity as Governor of the State of Nevada; RICHARD WHITLEY, in his official capacity as Director of the Nevada Department for Health and Human Services; and the NEVADA LEGISLATURE,

Defendants.

Case No.: 2:17-cv-02315-JCM-CWH

PLAINTIFFS' RESPONSE TO DEFENDANT NEVADA LEGISLATURE'S MOTION FOR LEAVE TO SUPPLEMENT SUMMARY-JUDGMENT RECORD; and

PLAINTIFFS' RENEWED MOTION FOR PRELIMINARY INJUNCTION

EXPEDITED TREATMENT REQUESTED
(RELIEF NEEDED BY July 1, 2018)

ORAL ARGUMENT REQUESTED

On May 3, 2018, the Nevada Legislature moved for leave to supplement the summary-judgment record with two items: (1) the Nevada Department of Health and Human Services' (the

"Department") proposed regulation to implement the challenged provisions of Senate Bill No. 539, and (2) the Department's notice of intent to act upon the proposed regulation, scheduling a public hearing for May 31, 2018. Plaintiffs do not object to including these regulatory materials in the summary-judgment record. The Department's proposed regulation, however, is just that: proposed. And because there is no guarantee—indeed, it is unlikely—that proposed regulations that adequately protect trade secrets will be approved before SB 539's July 1, 2018 reporting date, Plaintiffs' members now face the requirement to produce confidential materials on July 1 without the protection the regulations may ultimately provide against public disclosure. Therefore, to preserve the status quo pending resolution on the merits, Plaintiffs must renew their motion for a preliminary injunction against dissemination of manufacturers' trade secrets.

As the Court is aware, Plaintiffs previously moved for a preliminary injunction on September 13, 2017, at the outset of this litigation. Defendants opposed the motion primarily on the ground that irreparable harm was not imminent because, under the terms of SB 539, manufacturers would not have to disclose trade secrets to the Department until July 1, 2018. On that basis alone, the Court denied Plaintiffs' motion. The Court further acknowledged that Plaintiffs could appropriately renew their motion "next spring" in advance of the "harm [from] disclosure . . . which takes place in July." 10/18/2017 Hr'g Tr. 12 (ECF No. 62).

In the ensuing months, the parties briefed cross-motions for summary judgment that fully address the merits. (ECF Nos. 46, 66). The motions agreed on a central point: SB 539 cannot constitutionally require disclosure and publication of trade-secret information without sufficient protection of its confidentiality. Recognizing this reality, the Legislature argued that SB 539 does not, in fact, require the disclosure of trade secrets. Plaintiffs explained, however, that such an interpretation cannot be squared with SB 539's text. Pls.' Cross-Mot. for Summ. J. 10–14 (ECF No. 66); Pls.' Reply 6–11 (ECF No. 81). The Department agreed with this interpretation, acknowledging that SB 539 requires manufacturers to turn over their trade secrets to the State, but argued that it could cure this constitutional defect through regulations protecting the confidentiality of manufacturers' trade secrets. The Department requested that the Court "defer ruling on the

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Plaintiffs' claims until the Department has had an opportunity to adopt regulations to address [Plaintiffs'] trade secret concerns." AG's Resp. to Cross-Mot. for Summ. J. 6 (ECF No. 74). Plaintiffs doubted that the Department could adopt such regulations by July 1, 2018, but supported "deferring further litigation to allow the Department time to attempt a regulatory fix." Pls.' Reply 5 (ECF No. 81).

Today, the July 1 deadline for manufacturers to turn over trade-secret information to the Department is just weeks away, and the Department has not yet adopted any final regulation. *See* Nev. Rev. Stat. 233B.060 (prescribing administrative procedure for giving notice of intent to adopt proposed regulations, holding a hearing on the regulations, making potential revisions to the proposed regulations, and then adopting final regulations). Unless and until a final regulation ensuring the confidentiality of manufacturers' trade secrets is adopted, approved, and takes effect, the challenged provisions of SB 539 remain facially invalid for the reasons set forth in Plaintiffs' briefing on its cross-motion for summary judgment. *See* Pls.' Cross-Mot. for Summ. J. (ECF No. 66); Pls.' Reply (ECF No. 81).

As Plaintiffs explain in that briefing, SB 539 requires manufacturers to disclose their trade secrets to the Department, strips those companies of trade-secret protection for that information, and then requires the Department to publish a report on its website containing this formerly trade-secret information, organized by company. That mandate is unconstitutional for four reasons: (i) it conflicts with federal patent law, (ii) it conflicts with federal trade-secret law, (iii) it amounts to a "taking" without just compensation, and (iv) it violates the dormant Commerce Clause. Pls.' Cross-Mot. for Summ. J. 14–29 (ECF No. 66); Pls.' Reply 11–17 (ECF No. 81). In the proposed regulations, and in the Legislature's motion to supplement the record, both Defendants now agree that requiring disclosure of manufacturers' trade secrets would violate rights protected under federal trade secret law. The Supremacy Clause precludes such a displacement of federal law.

A final regulation that cures these constitutional defects almost certainly will not be in place by July 1, 2018, when Sections 3.8 and 4 of SB 539 will require pharmaceutical manufacturers to disclose trade secrets to the Department. Even if the Department adopts the regulation on May 31,

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2018, the regulation still must go to Legislative Counsel for review and to the Legislative Commission for approval. *See* Nev. Rev. Stat. 233B.067. At a May 16, 2018 meeting, the Legislative Commission acknowledged that it could not meet to approve the proposed regulations before June 26, 2018, just five days before the July 1 deadline for manufacturers to report their confidential information. If the Legislative Commission does not approve regulations that sufficiently protect trade secrets on that date, it would be difficult, if not impossible, for Plaintiffs to obtain relief before they have to turn over their confidential information. Moreover, Plaintiffs understand that if the Department, at the upcoming May 31 public hearing, suggests any substantive changes to the proposed regulation, it must go back to the Legislative Counsel Bureau, further delaying implementation of the final regulation.

As the Court is aware, Plaintiffs' members face imminent, irreparable harm if they are compelled to disclose trade secrets to the Department on July 1, 2018, without a final regulation in place ensuring confidentiality. *See* Tr. of Hr'g on Pls.' Mot. for Prelim. Inj. 10:14-18, 15:3-11 (ECF No. 62); Order Denying TRO at 3 (ECF No. 28) (finding no "immediate and irreparable injury" because manufacturers' "first round of disclosures to NDHHS are not due until July 1, 2018"); Pls.' Mot. Prelim. Inj. 22 (ECF No. 26). Because Section 9 of SB 539 strips manufacturers of trade-secret protection for this information, the Department will be allowed to publicly disclose confidential, proprietary, and competitively harmful information, and to use this information for its own benefit, such as in negotiating rebates with manufacturers. It also may allow private parties to access the information through public-records requests under the Nevada Public Records Act, which exempts from disclosure information "declared by law to be confidential," such as trade secrets, but otherwise makes available for inspection "all public books and public records of a governmental entity." Nev. Rev. Stat. § 239.010. While the Department currently acknowledges that federal law precludes it from disclosing manufacturers' confidential information, without a regulation in place binding the Department to that position, manufacturers cannot know when they produce their confidential information whether that position will change. In fact, without the process specified in the regulation

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allowing manufacturers the opportunity to seek judicial relief before disclosure occurs, manufacturers may learn the Department's views only after it releases the information.

In light of the Department's ongoing regulatory process and the upcoming July 1, 2018 deadline for manufacturers to submit reports to the Department and in order to preserve the status quo, Plaintiffs renew their motion for a preliminary injunction against dissemination of manufacturers' trade secrets. *See* Pls.' Reply 5–8 (ECF No. 81). Manufacturers of essential diabetes drugs cannot relinquish their trade secrets to the Department and then *hope* that the Department may adopt regulations that prevent them from being published online or otherwise disclosed. Pls.' Reply at 5 (ECF No. 81). The irreparable harm to manufacturers outweighs any potential harm to Defendants from a short delay in enforcement of the Act to allow the Department to adopt and implement final regulations protecting trade secrets. The public interest also strongly favors an injunction pending adoption of final regulations. Pls.' Mot. Prelim. Inj. 22–23 (ECF No. 26).

Accordingly, Plaintiffs respectfully request that the Court enter a temporary injunction prohibiting the Department from publishing, disseminating, or otherwise disclosing to any third party any information submitted to the Department pursuant to Sections 3.8 and 4 of SB 539 that the manufacturer designates as a trade secret. To designate information submitted to the Department as a trade secret, the manufacturer must mark the information as "CONFIDENTIAL – NOT TO BE DISCLOSED OR DISSEMINATED." Plaintiffs further request that the Court likewise hold the pending cross-motions for summary judgment in abeyance pending further Order of the Court following the Department's adoption of final regulation. The Court should further order the parties to submit a report to the Court after final regulations have been adopted explaining the parties' views

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on the implications of those regulations for the issues presented in the current litigation.

Dated: May 24, 2018.

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CERTIFICATE OF SERVICE

I certify that I am an employee of McDonald Carano, and that on the 24th day of May, 2018, a true and correct copy of the foregoing PLAINTIFFS' RESPONSE TO DEFENDANT NEVADA LEGISLATURE'S MOTION FOR LEAVE TO SUPPLEMENT SUMMARY-JUDGMENT RECORD; and PLAINTIFFS' RENEWED MOTION FOR PRELIMINARY INJUNCTION; EXPEDITED TREATMENT REQUESTED (RELIEF NEEDED BY July 1, 2018) was electronically filed with the Clerk of the Court by using CM/ECF service which will provide copies to all counsel of record registered to receive CM/ECF notification.

/s/ Beau Nelson
An Employee of McDonald Carano LLP

PROPOSED ORDER

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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA and BIOTECHNOLOGY INNOVATION ORGANIZATION,

Plaintiffs,

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BRIAN SANDOVAL, in his official capacity as Governor of the State of Nevada; RICHARD WHITLEY, in his official capacity as Director of the Nevada Department for Health and Human Services; and the NEVADA LEGISLATURE,

Defendants.

Case No.: 2:17-cv-02315-JCM-CWH

[PROPOSED] ORDER GRANTING PLAINTIFFS' RENEWED MOTION FOR PRELIMINARY INJUNCTION

Having considered all filings in support and opposition to Plaintiffs Pharmaceutical Research

and Manufacturers of America and Biotechnology Innovation Organization's ("Plaintiffs") Renewed Motion for Preliminary Injunction, and finding good cause appearing therefor,

IT IS HEREBY ORDERED:

1. That, pending further Order of this Court, the Nevada Department of Health and Human Services ("Department") is enjoined from publishing, disseminating, or otherwise disclosing to any third party any information submitted to the Department pursuant to Sections 3.8 and 4 of Nevada Senate Bill 539 ("SB 539") that the submitting pharmaceutical manufacturer designates as a trade secret;

2. That, for the purposes of this injunction, a pharmaceutical manufacturer shall designate information submitted to the Department as a trade secret by marking the submitted information as **"CONFIDENTIAL – NOT TO BE DISCLOSED OR DISSEMINATED"**;

3. That the parties' pending cross-motions for summary judgment (ECF Nos. 46 & 66) are held in abeyance pending further Order of this Court;

4. That each party shall submit a report to the Court (not to exceed 20 pages) within 28 days after final regulations implementing Sections 3.8 and 4 of SB 539 have been adopted; the report should explain that party's view on the implications of the final regulations for the pending cross-motions for summary judgment; and

5. That the parties shall submit a joint status report on October 1, 2018, in the event that no final regulations implementing Sections 3.8 and 4 of SB 539 have been adopted by that time.

It is SO ORDERED this _____ day of _____, 2018.

_____
United States District Judge

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